REMARKS

Reconsideration is requested.

Claims 19-21, 28 and 32 have been canceled, without prejudice.

The details of claims 28 and 32 have been added to claims 22 and 29. The withdrawn claims have been similarly amended. No new matter has been added.

The Examiner's "reminder" to cancel non-elected subject matter (see, page 2 of the Office Action dated September 10, 2004) is not completely understood and clarification is requested as the Examiner stated on page 3 of the Office Action dated October 2, 2003 that "Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim." Clarification is requested.

The Office is again requested to acknowledge receipt of the priority document from the International Bureau as the Office Action of September 10, 2004, does not indicate the same and the Office Action of December 17, 2003, indicates that the acknowledgement of the claim for foreign priority is made and that "all" of some documents have been received. Specifically, page 2 of the Office Action dated December 17, 2003, does not include a complete statement with regard to the ticked boxes relating to receipt of the priority document. A complete Action in this regard will be appreciated.

The Examiner is requested to acknowledge the acceptance of the formal drawings and/or provide a specific objection or rejection of the same.

The Examiner is also requested to return an initialed copy of Form PTO-1449, filed with an Information Disclosure Statement on September 4, 2001, to the undersigned. A copy of the same was not received with the Office Action dated September 10, 2004 or previously-issued Office Actions. A further copy of Form PTO-1449 filed September 4, 2001 was filed with the applicants Request of September 23, 2004.

The Section 112, first paragraph, rejection of claims 22-29 stated in ¶6 of the Office Action dated September 10, 2004 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments.

The present specification discloses that a leukemia cell line can be detected by the antibody of the present invention. Accordingly, it will be appreciated by one of ordinary skill in the art that an antibody of the present invention binds to leukemia cell lines. Regarding ADCC activity, one of ordinary skill in the art will further appreciate that the antibody binds to a target cell to thereby cause cellular cytotoxic activity of an effector cell such as leukocyte via the Fc region, and thus the target cell is injured. The ordinarily skilled person will also appreciate the ability of the antibody in the ADCC activity. For example, the attached document, Grossbard et al., Blood, 80, 863 (August 15, 1992), explains at Fig. 1 and page 863, left col., line 36 to page 864, right col. line 2, for example, that by contrast, antibody-dependent cell-mediated cytotoxicity (ADCC), in which lymphocytes recognize the Fc region of cell-bound antibody and are triggered to kill the target cell, is most effective with murine antibodies of the IgG2a and IgG3 isotype.

Accordingly, the ordinarily skilled person will understand from the advanced knowledge in the art at the time of the present invention, and the present specification, the relationship between the fact that the antibody of the present invention can detect leukemia cell lines and the fact that the antibody of the present invention has ADCC activity against leukemia cell lines. Furthermore, since the antibody of the present invention actually has ADCC activity against leukemia cell lines, it is apparent that the antibody of the present invention may be reasonably used for treating leukemia.

The Examiner will appreciate that leukemia is a disease in which leukocytes in blood are increased, and most of the leukocytes which are the cause of the disease are present in vascular flow. Since the antibody of the present invention has ADCC activity against leukemia cell lines, the ordinarily skilled person will appreciate that the antibody of the present invention injures leukocytes present in vascular flow and may be used in treatment of leukemia, with no more than a reasonable amount of experimentation.

Based on the above, the applicants submit that one of ordinary skill will understand that an antibody of the present invention can bind to leukemia cell lines and that leukemia can be treated by an antibody of the present invention.

Withdrawal of the Section 112, first paragraph, rejection stated in ¶6 of the Office Action dated September 10, 2004, is requested.

As for the Examiner's comments on pages 4-5 of the Office Action dated September 10, 2004, relating to separate "interpretation" of the claims based on the statutory section being analyzed for compliance, consideration of the following and MPEP §2100 is requested.

The claims define the property rights provided by a patent, and thus require careful scrutiny. The goal of claim analysis is to identify the boundaries of the protection sought by the applicant and to understand how the claims relate to and define what the applicant has indicated is the invention. "**Patent Examiners must first determine the scope of a claim by thoroughly analyzing the language of the claim before determining if the claim complies with each statutory requirement for patentability.**" See, MPEP § 2100. See also, In re Hiniker Co., 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998) ("[T]he name of the game is the claim.").

The apparent separate interpretation or analysis by the present Examiner depending on whether compliance with Section 102 or Section 112 is being analyzed is inappropriate and contrary to the law and Rules. See, pages 4-5 of the Office Action dated September 10, 2004 ("For purposes of the instant rejection [of claims 22-29 under Section 112, first paragraph], the claims are read to the extent that the method is drawn to a method of treating diseases associated with a tumorigenic change to a hematopoietic cell. On the other hand, the art rejection under 35 USC 102(e) [the claims are] is [sic] read to the extent the claims read on the administration of an anti-flt1 antibody to a patient. Because the **interpretation** of the claims for the 102(e) rejection only requires a single step (i.e. administration to a patient) and does not specifically limit the type of patient to which the administration is to take place, the art does not enable the instant invention to the extent that is {sic, it} reads on treating a disease associated with a tumorigenic change in a hematopoietic cell." (emphasis added).

Contrary to the Examiner's assertions, the unamended claim 22, for example, required administration to a "patient in need thereof" where one of ordinary skill in the

art will appreciate that the patient are those in need of treatment of a disease caused by the tumorigenic change of a hematopietic cell. More importantly, the Examiner's separate "interpretation" of the claims dependent on the statutory provision being analyzed is inappropriate.

Office personnel should begin claim analysis by identifying and evaluating each claim limitation. For processes, the claim limitations will define steps or acts to be performed. For products, the claim limitations will define discrete physical structures or materials. Product claims are claims that are directed to either machines, manufactures or compositions of matter. The discrete physical structures or materials may be comprised of hardware or a combination of hardware and software.

Office personnel are to correlate each claim limitation to all portions of the disclosure that describe the claim limitation. The correlation step will ensure that Office personnel correctly interpret each claim limitation.

The subject matter of a properly construed claim is defined by the terms that limit its scope. <u>It is this subject matter that must be examined.</u>

Office personnel must rely on the applicant's disclosure to properly determine the meaning of the claims. Markman v. Westview Instruments, 52 F.3d 967, 980, 34 USPQ2d 1321, 1330 (Fed. Cir.) (en banc), aff'd, U.S. , 116 S. Ct. 1384 (1996). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298, 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)("In the absence of an express intent to impart a novel meaning to the claim terms, the words

are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art.") However, an applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning. See In re Paulsen, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).< Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. Toro Co. v. White Consolidated Industries Inc., 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings."). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." Multiform Desiccants Inc. v. Medzam Ltd., 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). See also MPEP § 2111.01.

Office personnel must always remember to use the perspective of one of ordinary skill in the art. Claims and disclosures are not to be evaluated in a vacuum. If elements of an invention are well known in the art, the applicant does not have to provide a disclosure that describes those elements.

Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. >E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d

1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily).< In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.").

While it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not impose that limitation. A broad interpretation of a claim by Office personnel will reduce the possibility that the claim, when issued, will be interpreted more broadly than is justified or intended. An applicant can always amend a claim during prosecution to better reflect the intended scope of the claim.

Finally, when evaluating the scope of a claim, every limitation in the claim must be considered. Office personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered. See, e.g., Diamond v. Diehr, 450 U.S. at 188-89, 209 USPQ at 9 ("In determining the eligibility of respondents' claimed process for patent protection under 101, their claims must be considered as a whole. It is inappropriate to dissect the

claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.").

Prior to classifying the claimed invention under 35 U.S.C. 101, Office personnel are expected to conduct a thorough search of the prior art. Generally, a thorough search involves reviewing both U.S. and foreign patents and nonpatent literature. In many cases, the result of such a search will contribute to Office personnel's understanding of the invention. Both claimed and unclaimed aspects of the invention described in the specification should be searched if there is a reasonable expectation that the unclaimed aspects may be later claimed.

The above procedures and guidelines for examination of applications are generally and specifically described in Chapter 2100 of the MPEP which further includes a description of the process for evaluating whether the applicants have complied with the further statutory requirements, which include Sections 112 and 102. In the event the Examiner continues to interpret the claims in a different manner based on the statutory section being evaluated, the Examiner is requested to advise the undersigned where authority exists in the Law, Rules, MPEP and/or Court decisions for such a separate evaluation.

Rather, as noted above, the courts have made clear that claims are interpreted and then examined for their compliance with the statutory requirements. In the case of Section 102, an anticipatory reference must teach each and every element of the claimed invention. The Examiner's "enablement" rejection of claims 22-24 therefore is

inconsistent with the Examiner's Section 102 rejection of claims 22-24 over Shitara (U.S. Patent No. 6,617,160) as if the cited art does in fact place the presently claimed invention in the art, as the Examiner asserts in the Section 102 rejections of claims 22-24, then one of ordinary skill is presumably also taught how to make and use the claimed invention. Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research, 68 USPQ2d 1373, 1375 (CA FC 2003) ("To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. 'A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled.' " *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). *See Bristol-Myers Squibb v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) ("To anticipate the reference must also enable one of skill in the art to make and use the claimed invention."); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.")).

Withdrawal of the Section 112, first paragraph, rejection stated in ¶6 of the Office Action dated September 10, 2004, is requested.

The provisional obviousness-type double patenting rejection of claims 22-28 over claims 1, 6, 7, 10, 34 and 49-50 of application Serial No. 10/160,232 "in view of" (see, page 6 of the Office Action dated December 17, 2003) claims 3-5 and 9 of application Serial No. 10/009,723, is traversed.

Withdrawal of the provisional obviousness-type double patenting rejection is requested as, at a minimum, the provisional rejection is contrary to the Examiner's restriction requirement. Specifically, the Examiner has suggested in the present application that the methods of the present claims are allegedly separately patentable from the products (i.e., diagnostic agents and therapeutic agents) and other methods (i.e., method for diagnosing a disease) of the claimed invention. See also page 2 of the Office Action dated October 2, 2003. At the same time, the Examiner has rejected the presently claimed method of treating a disease over product claims 1, 6, 7, 10, 34 and 49-50 of the co-pending application Serial No. 10/160,232 (the Examiner is requested to note that claims 49-50 have been canceled from the co-pending application Serial No. 10/160,232) "in view of" product claims 3-5 and 9 of the co-pending application Serial No. 10/009,723. It is unclear to the undersigned how claims to products and methods could be held separately patentable by the Examiner for purposes of restriction and then allegedly obvious in view of each other during examination. Clarification or withdrawal of the provisional obviousness-type double patenting rejection of claims 22-28 is requested.

The undersigned notes, for completeness, that the Examiner's assertion that "US Application No. 10/160232 ... claims a method of treating disease ...", as a basis for the provisional obviousness-type double patenting rejection, is not believed to be correct. See, page 6 of the Office Action dated December 17, 2003. Moreover, the undersigned notes that claims 3-5 and 9 of the co-pending application Serial No. 10/009,723 are not believed to claim "that a human VEGF receptor flt-1 antibody can be used as a reagent

that is capable of reacting with hematopoietic cells..." as suggested on page 6 of the Office Action dated December 17, 2003.

Withdrawal of the provisional obviousness-type double patenting rejection is requested. At a minimum, the Examiner is requested to hold the provisional rejection in abeyance until such time as allowable subject matter is identified.

The Section 102 rejection of claims 22-24 over Shitara (U.S. Patent No. 6,617,160) is obviated by the above amendments. Withdrawal of the rejection is requested.

The Section 112, first paragraph, rejection of claim 22-32 stated in ¶10 of the Office Action dated September 10, 2004 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above and the following comments.

The Examiner's concerns regarding the treatment of diseases other than leukemia are moot in view of the above.

With regard to the amounts of the antibody, the applicants submit that the ordinarily skilled person would appreciate from, for example, the description at page 50, lines 19 to 23, that the applicants were in possession of the claimed invention.

With regard to the Examiner's apparent concerns relating to the protein of claim 27, the applicants submit that the ordinarily skilled person would appreciate that the applicants were in possession of the claimed invention from, for example, the description at page 47, lines 8-20 in the specification and technical common knowledge at the time the present application was filed. Also, with regard to the low molecular weight agent in claim 27, the anticancer agent is exemplified at page 47, line 22 of the present specification. An ordinarily skilled person would understand the term based on

the description at, for example, page 47, lines 8 to 24 in the specification and technical common knowledge at the time the present application was filed and appreciate that the applicants were in possession of the claimed invention.

Withdrawal of the Section 112, first paragraph, rejection of claims 22-32 stated in ¶10 of the Office Action dated September 10, 2004, is requested.

The Section 102 rejection of claims 22-23, 25-27, 29 and 30-31 over Rockwell (U.S. Patent No. 5,840,301) is obviated by the above amendments. Withdrawal of the rejection is requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned in the event anything further is required.

Respectfully submitted,

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